

Application No. 09/960,260
Amendment dated JUNE 14, 2006
Reply to Office Action dated March 14, 2006

REMARKS

Applicants have carefully reviewed the Office Action dated March 14, 2006. Claims 1-31 are pending in the application, in which claims 9-11, 13, 16, 17, 19 and 20 are withdrawn from consideration, claims 1-8, 12, 14, 15, 21-24 and 29 are rejected and claims 18, 25-28, 30 and 31 are objected to. Claims 5-8, 18, 30 and 31 have been amended with this Response. No new matter has been added.

Allowable Subject Matter

Claims 18, 25-28, 30 and 31 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 18, 30 and 31 have been rewritten in independent form, and as such, these claims are believed to be in condition for allowance. Additionally, because they are dependent on now independent claim 18, and because they contain additional patentably distinct elements, Applicants submit that claims 25-28 are also allowable.

Double Patenting

Claims 1-8 and 15 are provisionally rejected on the ground of statutory obviousness-type double patenting as being unpatentable over claims 1-8 and 16 of co-pending Application No. 10/244,870. As the cited reference is pending, Applicants defer a possible Terminal Disclaimer until issuance of the reference.

Drawings

The drawings are objected under 37 CFR 1.83(a). Specifically, it was asserted that the drawings do not show each and every element of claims 18, 25 and 28. These claims all recite, in part, that the IFM comprises "one or more rings". In 37 C.F.R. 1.83(a), it is stated "the drawing in a nonprovisional application must show every feature of the invention specified in the claims." In the Office Action, it is stated that the feature "more rings" is not shown in the figures. However, the claim actually recites "one or more rings", and Applicants

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respectfully assert that the drawings do show "one or more rings", for example in Figures 1 and 2. As such, Applicants respectfully submit that the drawings are proper in their current form. Withdrawal of the objection is respectfully requested.

Claim Objections

The Examiner Objected to claims 5-8 and 29 for informalities, indicating that the claims were not proper because they claim the combination of the intravascular device and the packaging lumen whereas claim 1 is directed to the subcombination of the intravascular device. While not necessarily agreeing with the objection, in the interest of furthering prosecution, claims 5-8 and 29 have been amended in order to clarify that the claims are directed to an intravascular device, as is claim 1, and not to a combination of the intravascular device and the packaging lumen. Applicants respectfully assert that the claims 5-8 and 29 are consistent with the remainder of the claim set in that they are directed to an intravascular device. While the preamble of claim 1 recites a package lumen defined by a package lumen wall, as indicated by the Examiner, claim 1 is drawn to an intravascular device. In other words, the package lumen and package lumen wall in the preamble of claim 1 are not part of the claimed structure of claim 1, but instead are introduced in the preamble and are used to assist in defining the structure of the claimed intravascular device. In claims 5-8 and 29, the package lumen and/or the package lumen wall are used in a similar manner - to assist in further defining the claimed structure – which is an intravascular device. The manner in which claims 5-8 and 29 are written, and the fact that they are dependent upon claim 1, make it clear that the package lumen and/or package lumen wall are not part of the claimed structure, but rather are provided in order to help further define the claimed intravascular device. Claims 5-8 and 29 may include additional language regarding the package lumen and/or the package lumen wall, but such language is simply adding to the preamble of claim 1, and is used to help further define the claimed structure – an intravascular device. Thus, Applicants respectfully request withdrawal of this objection.

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Claim Rejections under 35 U.S.C §112

Claims 5-8 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it was asserted that these claims are positively claiming the "package lumen", while there is no positive recitation in claim 1 for the "package lumen." It is noted that claims 5-8 have been amended, as set forth above, to help clarify. As mentioned above, these claims depend from claim 1, and the preamble of claim 1 recites a package lumen and package lumen wall - not as positive elements of the claim, but rather in order to help further define the claimed intravascular device. Applicants respectfully submit that dependent claims 5-8 make similar use of the recited package lumen and/or package lumen wall language. Like claim 1, claims 5-8 are not positively reciting the package lumen and/or the package lumen wall, but rather are using the language from the preamble of claim 1 in order to help further define the claimed intravascular device. Claims 5-8 may include additional language regarding the package lumen and/or the package lumen wall, but such language is not being positively recited, but rather is simply adding to the preamble of claim 1, and is used to help further define the claimed structure - an intravascular device. Thus, Applicants respectfully submit that these claims do comply with 35 U.S.C. §112, second paragraph. Thus, Applicants respectfully request withdrawal of this rejection.

Claim Rejections under 35 U.S.C §102

Claims 1-8, 12, 14, 15, 21-24 and 29 have been rejected under 35 U.S.C. §102(b) as being anticipated by Dietrich, U.S. Patent No. 3,720,210. Applicants respectfully traverse this rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference. See M.P.E.P. §2131.

Dietrich apparently discloses a catheter needle assembly 10 including an indwelling catheter device 12, a needle 18, a shield or cover 20 and a plug 22. The indwelling catheter device 12 has a hub element 14 and an elongated flexible tubular catheter section 16. The needle 18 extends through the hub element and catheter sections (14, 16) of indwelling catheter device 12. The shield or cover 20 is mounted on the hub element 14 in a manner to protect the catheter section 16 and the exposed portion of the needle 18. The plug 22 is

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inserted in the open end or mount of the hub element 14. See column 3, lines 2-11 of Dietrich for a description of this catheter needle assembly 10. Applicants respectfully disagree that Dietrich discloses each and every element of claims 1-8, 12, 14, 15, 21-24 and 29.

Independent claim 1 recites, in part, an intravascular device suitable for packaging in a package lumen defined by a package lumen wall, the device comprising an elongate shaft and a hub assembly. The hub assembly is connected to the proximal portion of the elongate shaft, and the hub assembly includes an interference fit member (IFM) which is configured to form an interference fit with the package lumen wall when the intravascular device is disposed in the package lumen. The Office Action is apparently stating that the shield or cover 20 of Dietrich is both the interference fit member and the package lumen. However, claim 1 recites these structures as two separate structures, and Applicants therefore assert that the shield or cover 20 cannot be both the interference fit member and the package lumen. In addition, claim 1 recites that the IFM is configured to form an interference fit with the package lumen wall. If the shield or cover 20 of Dietrich is both the IFM and the package lumen, Applicants do not see how the shield or cover 20 of Dietrich forms an interference fit with itself.

In fact, nothing in Dietrich describes such an interference fit between a package lumen and an IFM. It appears as though the only portion of Dietrich that describes an interference fit is in the forming of a fluid-tight interference fit when the collar member 26 is mounted over the elongate flexible tube section 16. See column 4, lines 2-7. Because Dietrich does not disclose an IFM that is configured to form an interference fit with a package lumen, Dietrich does not disclose each and every element of independent claim 1.

For at least the above reasons, Applicants assert that claim 1 is allowable over Dietrich. Because they are dependent on claim 1 and because they contain additional patentably distinct elements, Applicants assert that claims 2-8, 12, 14, 15 and 29 are also allowable. Thus, Applicants respectfully request withdrawal of this rejection.

Claim 21 recites a hub assembly for an intravascular device that is suitable for packaging in a carrier tube, the hub assembly comprising an IFM which is configured to form an interference fit with the carrier tube. It is unclear from the Office Action what structures

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are being equated with the IFM and the carrier tube of claim 21. "Where a claim is refused for any reason relating to the merits thereof it should be 'rejected' and the ground of rejection fully and clearly stated" in order to provide for a *prima facie* case of anticipation. M.P.E.P. §707.07(d). Applicants respectfully assert that the Examiner has not met this standard. In fact, all elements of claim 21 are not even discussed in the Office Action. For example, the carrier tube of claim 21 is not compared to anything in Diettrich. Thus, Applicants assert that a *prima facie* case of anticipation has not been shown by the Examiner.

However, it appears as though the Office Action may be interpreting the shield or cover 20 of Diettrich as both the IFM and carrier tube of claim 21. If so, Applicants point out that the IFM of claim 21 is recited as forming an interference fit with the carrier tube. These are separate elements, and thus Applicants respectfully assert that they cannot be equated with a single element 20 of Diettrich. Also, Applicants do not see how the shield or cover 20 of Diettrich can form an interference fit with itself, and therefore this element cannot be both the carrier tube and the IFM (which forms an interference fit with the carrier tube) of claim 21. In fact, as mentioned above with respect to claim 1, Diettrich does not appear to disclose anything about an IFM forming an interference fit with any other structure. For at least the above reasons, Applicants assert that claim 21 is allowable over Diettrich. Thus, Applicants respectfully request withdrawal of this rejection.

Claim 22 recites, among other elements, a hub assembly including a means for forming an interference fit with the package wall. Again, it is not clear what structures are being equated with the means for forming an interference fit. The Office Action does not compare any structures of Diettrich with the means of claim 22, and thus Applicants respectfully assert that a *prima facie* case of anticipation has not been shown. See M.P.E.P. §707.07(d) and §2183. Also, as mentioned above with respect to claim 1, there is nothing in Diettrich that teaches an IFM that is configured to form an interference fit with a package lumen. Similarly, there is nothing in Diettrich that teaches a means for forming an interference fit with a package lumen wall. For at least the above reasons, Applicants assert that claim 22 is allowable over Diettrich. Thus, Applicants respectfully request withdrawal of this rejection.

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Claim 23 recites, in part, a means for forming an interference fit with a package wall. Again, it is not apparent what structure is being equated with the means for forming an interference fit with a package wall and, again, Applicants respectfully assert that a *prima facie* case of anticipation has not been shown because no structures of Dietrich have been compared to the means of claim 23. Also as mentioned above with respect to claim 22, nothing in Dietrich discloses a means for forming an interference fit with a package wall, as required by claim 23. For at least the above reasons, Applicants assert that claim 23 is allowable over Dietrich. Thus, Applicants respectfully request withdrawal of this rejection.

Claim 24 recites, among other elements, an IFM that is configured to form an interference fit with a package lumen wall. With respect to this claim, it appears as though the cover or shield 20 is being equated with both the package lumen and the interference fit member. However, claim 24 recites the interference fit member and the package lumen as two separate structures, and Applicants therefore assert that the shield or cover 20 cannot be both the interference fit member and the package lumen of claim 24. In addition, claim 24 recites that the IFM is configured to form an interference fit with the package lumen. If the shield or cover 20 of Dietrich is both the IFM and the package lumen, Applicants do not see how the shield or cover 20 of Dietrich forms an interference fit with itself. Also, as mentioned above with respect to claim 1, Dietrich does not appear to disclose an IFM that is configured to form an interference fit with a package lumen at all. For at least the above reasons, Applicants assert that claim 24 is allowable over Dietrich. Thus, Applicants respectfully request withdrawal of this rejection.

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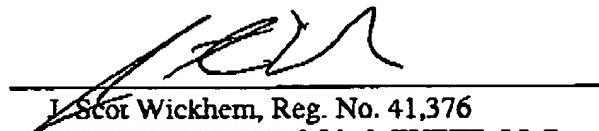
Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their attorney,

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